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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/505,474 | 08/24/2004 | Akira Tsukamoto | 04853.0118 | 8917 |
| 22852 7590 10/01/2007 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413 | | | EXAMINER EPPS FORD, JANET L | |
| | | | ART UNIT 1633 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/505,474

Applicant(s)

TSUKAMOTO ET AL.

Examiner

Janet L. Epps-Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7-23-07.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 5-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4 and 10-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-14 are presently pending.
2. Claims 3, and 5-9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2-09-07.
3. Claims 1-2, 4, and 10-14 are presently pending for examination.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

Claim Rejections - 35 USC § 112

5. Claims 1-2, 4, and 10-14 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record.
6. Applicant's arguments filed 7-23-07 have been fully considered but they are not persuasive. Applicants traversed the instant rejection on the grounds that since the examiner recognizes that the instant claims are drawn to a genus, that the disclosure of wherein the cellobiohydrolase I gene comprises a nucleotide sequence as shown in SEQ ID NO: 7, 9 or 11, is sufficient to describe the broad genus of antisense RNA *substantially complementary* to all or part of a transcription product of a cellulolytic

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enzyme gene *derived* from Basidiomycetes, wherein said antisense RNA functions to suppress cellulolytic enzyme activity.

7. The specification as filed at paragraph [0169] states: “[M]oreover, the term “substantially” is used herein to mean that as long as the antisense RNA binds to mRNA to form a double strand and it inhibits the translation of mRNA into a protein, the sequence may comprise a mutation such as deletion, substitution, or addition.”

8. Contrary to Applicant’s assertions, Applicant’s disclosure of 3 forms of cellobiohydrolase I isolated from a single species of Basidiomycetes, namely *Coriolus hirsutus*, is not sufficient to predict the full scope of potential antisense RNA that are “substantially” complementary to a cellulolytic enzyme derived from the Basidiomycetes class of fungi. Moreover, it is noted that the metes and bounds of the phrase “derived from” is not adequately described. This phrase may also include cellulolytic enzyme genes comprising additions, deletions, and various mutations, wherein the antisense RNA of the invention are substantially complementary to a transcription product of these sequences. It is clear that further experimentation would be required to fully identify the full scope of the claimed antisense RNA used in the methods of the claimed invention.

Applicants have not described the structures of the full scope of cellobiohydrolase 1 genes encompassed by the instant claims, such that the skilled artisan would be able to predict the structures of the full scope of antisense constructs encompassed by the instant claims. This conclusion is based upon the observation that, other than the full-length sequences of SEQ ID NO: 7, 9, or 11, wherein said sequences have cellobiohydrolase 1 activity, the specification as filed does not provide

a clear correlation between modified, mutated, polymorphic, or allelic variant forms of these sequences, wherein said sequences comprises deletions, substitutions or additions, and maintains cellobiohydrolase 1 activity. Moreover, to the extent that Applicants are not in possession of the full scope of nucleic acid sequences encoding modified, mutated, polymorphic, or allelic variants of cellobiohydrolase 1 encompassed by the instant claims, Applicants are not in possession of the full scope of antisense constructs encompassed by the instant claims which target the full scope of nucleic acid sequences having cellobiohydrolase 1 activity.

See the January 5, 2001 (Vol. 66, No. 4, pages 1099-1111) Federal Register for the Guidelines for Examination of Patent Applications Under the 35 USC 112 ¶ 1, "Written Description" Requirement. These guidelines state: "[T]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that applicant was in possession of the claimed invention."

See also MPEP § 2163, which states “[A] biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.”

In the instant case, since Applicants have not provided sufficient description to clearly demonstrate a correlation between the nucleotide sequence structures

Claim Rejections - 35 USC § 102

9. Claims 12-14 remain rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. (1995; see IDS), for the reasons of record.

10. Applicant's arguments filed 7-23-07 have been fully considered but they are not persuasive. Applicants argue that because claim 1 was not rejected the process of claim 1 is not taught; therefore the woodchip, pulp, and method recited in claims 12-14 are not anticipated.

11. Contrary to Applicant's assertions, claims 12 and 14 are product by process claims. Since the prior art discloses wood chips, wherein these wood chips are treated with the Basidiomycete *P. chrysosporium* to produce pulp, absent evidence to the contrary the wood chips and pulp disclosed in Chen et al. meet the limitations of the instant claims, although they were produced by a different method. See MPEP § 2113 [R-1], which recites: “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in

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the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

13. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Ford/
Primary Examiner
Art Unit 1633

JLE

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